

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

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Device Name:

- Trade Name - System B HeatSource
- Common Name - Dental Instrument Heater
- Classification Name - Pulp Tester, per 21 CFR § 872.1720

Devices for Which Substantial Equivalence is Claimed:

- Analytic Technology Corporation, Touch N' Heat

Device Description:

The device is a battery-operated dental instrument heater which is designed to provide continuous heat at the tip of a dental instrument, the Hot Pulp Test Tip and the Caulerizing Tip, to test tooth response to thermal stimulus and for tissue cauterization and coagulation, respectively. The battery is fully rechargeable through the use of the plug-in charge adapter. The temperature is regulated by a feedback control system which automatically maintains a preset temperature for consistent results. The handpiece and cord assembly are completely removable. Both the handpiece and cord assembly and the dental instruments used with the device are autoclavable.

Intended Use of the Device:

The intended use of the dental instrument heater is to provide continuous heat at the tip of a dental instrument, the Hot Pulp Test Tip and the Caulerizing Tip, to test tooth response to thermal stimulus and for tissue cauterization and coagulation.

Substantial Equivalence:

The dental instrument heater is substantially equivalent to several other legally marketed devices in the United States. The dental instrument heater marketed by Analytic Technology Corporation functions in a manner similar to and is intended for the same use as the product manufactured by Analytic Technology Corporation.

Section I - Indications for Use

510(k) Number: K970715

Device Name: System B HeatSource, Model 1005

Indications for Use:

The System B HeatSource, Model 1005, is intended to be used in dentistry to provide continuous heat at the tip of a dental instrument to test tooth response to thermal stimulus and for tissue cauterization and coagulation.